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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,752	12/08/2008	Martin Imhof	PT-3464-US-PCT (27214-15)	1141

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Smith & Nephew, Inc.
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EXAMINER	
HOFFMAN, MARCIA	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
10/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/596,752	IMHOF, MARTIN	
	Examiner	Art Unit	
	MARCIA HOFFMAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-34* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10 and 12-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/10/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/10/2010 has been entered.

2. Claims 5-35 are pending. Claim 11 is withdrawn from further consideration. Claims 26-35 are new.

Response to Arguments

3. Applicant's arguments filed 09/10/2010 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 5-10 and 12-25 have been considered but are moot in view of the new ground(s) of rejection, including further interpretations of Serbousek et al. U.S. publication no. 2002/0068980.

Claim Objections

4. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 recites "the joint socket and the joint insert are configured to allow free rotation and tilting of the insert in the socket shell when the insert and shell are in contact with each other along the line of contact," while claim 5, upon which claim 12 depends, defines contact at the line of contact as being self-locking, which would prohibit free

rotation and tilting of the insert in the socket shell when the insert and shell are in contact with each other along the line of contact.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5-10, 12-29 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 6 and 21 recite "an infinite radius of curvature", wherein it is unclear if this is the same as "a radius of curvature" recited claims 5 (line 14-15) and 19 (lines 12-13) upon which these claims respectively depend.

8. Claims 5, 19 and 34 are unclear as each recites "a radius of curvature" in lines 14-15, 12-13, and 10 respectively, wherein such a recitation appears to imply curvature wherein said portions are not disclosed as being curved.

9. Regarding claim 12 it is unclear how the joint socket and the joint insert are configured to allow free rotation and tilting of the insert in the socket shell when the insert and shell are in contact with each other along the line of contact.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 5-10, 12, 14-17, and 19-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Serbousek et al. U.S publication no. 2002/0068980.

12. Regarding claims 5 and 19-20, Serbousek et al. disclose a joint socket (10) for a hip endoprosthesis (i.e. acetabular cup assembly), comprising: a socket shell (12) configured to be implanted in the pelvic bone of a patient (paragraph [0029], lines 3-4), the socket shell having an inner surface (20) that defines an accommodating space (24) extending about an axis of rotation (figure 1); and a socket insert (14) configured so as to be capable of providing a bearing for a joint head of a prosthesis stem via a bearing surface (34), a spherical outer surface of the socket insert configured to be disposed or inserted in the accommodating space (24) of the socket shell (12) (figures 1 and 3) and contact the inner surface of the socket shell along a line of contact that is concentric with the axis of rotation of the accommodating space of the socket shell (interpretation 1: see figures 2-4, wherein a spherical outer surface (32) of the socket insert is configured to be disposed or inserted into the accommodating space (26) of the socket shell and contact an inner surface (20) of the socket shell along a (any) line of contact that is concentric with the axis of rotation of the accommodating space; interpretation 2: see paragraph [0029], lines 21-24, and paragraph [0030], lines 1-4, where a spherical outer surface of the socket insert is defined as including at least the circumferential (edge) transition between a taper portion and hemi-sphere, such that a spherical outer surface, particularly at this transition of the socket insert is configured to be disposed or inserted in the accommodating space of the socket shell and contacts the inner surface of the socket shell along a line of contact that is concentric with the axis of rotation of the accommodating space of the socket shell –interpretation 2 particularly supported by Applicant's remarks such that the region of the outer spherical surface contacts the

taper portion of the inner surface of the socket- interpretation 3: see paragraph [0034], lines 7-11, paragraph [0035], lines 18-21, and paragraph [0040], lines 7-10, wherein it is within the scope of the disclosure to have a spherical outer surface of an insert in self-locking contact with a straight inner surface of an acetabular shell as the line of contact), the line of contact described in each of interpretations 1-3 above being surrounded by and intersecting the spherical outer surface of the socket insert, the socket insert *coupleable* in a self-locking manner *within* the accommodating space along the line of contact (figures 1-4; paragraphs [0035] and [0040]), wherein the inner surface (at 30) of the socket shell (12) tapers toward a pole of the shell (figure 4) in *a region* on either side of the line of contact in such a manner that a radius of curvature of the taper of the inner surface of the socket shell in the region of the line of contact is greater than the spherical radius of the outer surface of the socket insert at the line of contact when the shell and insert are in contact with each other (i.e. sized such that the insert is capable of entering the socket).

13. Regarding claims 6 and 21, Serbousek et al. disclose the inner surface has a conical shape (paragraph [0034], lines 7-9) and defines an infinite radius of curvature in the region of the line of contact (figures 2-4).

14. Regarding claims 7 and 22, Serbousek et al. disclose a cone angle of the conically shaped inner surface is a self-locking angle (paragraph [0035], lines 5-11) corresponding to a material pairing of the socket shell and the socket insert (paragraph [0033], where it is understood that material pairing is necessary in combining materials and interlocking components and would thus also be necessary in affixing shell and liner).

15. Regarding claims 8-10 and 23-25, Serbousek et al. disclose the cone angle of the conical inner surface is between about 4° and 10°, or particularly about 4.5° degrees, or particularly about 9.5° (paragraph [0035]).

16. As best understood, regarding claim 12, Serbousek et al. disclose the joint socket and the joint insert are configured to allow free rotation and tilting of the insert in the socket shell (paragraph [0040], lines 7-10) -- when inserting, removing or positioning, i.e. including a point in time wherein the shell and liner are in contact but not fully locked into place (figures 2-4).

17. Regarding claim 14, Serbousek et al. disclose the socket shell is configured to be fixed in a bone by one or more screws (figures 7-9, where it is understood that the socket shell is configured such that it is capable of being fixed in a bone by one or more screws –paragraphs [0041]-[0042]--, wherein the use of bone screws to secure a socket shell is well-known in the art).

18. Regarding claim 15, Serbousek et al. disclose the accommodating space comprises a generally flat base (22) (figure 4; paragraph [0029], lines 17-20).

19. Regarding claim 16, Serbousek et al. disclose the socket insert is a metallic socket insert (paragraph [0031], lines 13-14).

20. Regarding claim 17, Serbousek et al. disclose the socket insert is a ceramic socket insert (paragraph [0031], lines 13-15).

21. Regarding claims 30-31 and 34-35, Serbousek et al. disclose a joint socket (10) for a hip endoprosthesis (i.e. acetabular cup assembly), comprising: a socket shell (12) having an inner surface (20) that defines an accommodating space (24) extending about an axis of rotation (figure 1), at least a portion of the accommodating space (via 30) is conical or in the form of a

straight circular cone (figure 4) having a tapered portion that extends about the axis of rotation (paragraph [0034]), the straight circular cone having a cone angle between about 4 degrees and 10 degrees (paragraph [0035]); and a socket insert (14) having an outer surface (including 44), the outer surface is spherically shaped with a radius of curvature (paragraph [0034], particularly lines 7-11, and paragraph [0035], particularly lines 18-21) at least in a region in which the outer surface of the socket insert comes into contact with the inner surface of the straight circular cone in use (figure 4 in view of above citations), wherein the socket shell and insert are coupleable in a self-locking manner along a contact between the spherically shaped region and the circular cone portion (paragraphs [0034]-[0035] and [0040], lines 7-10), that is, the socket insert is configured to contact the socket shell on the tapered portion along a line of contact concentric with the axis of rotation of the tapered portion when the socket insert is inserted into the accommodating space of the socket shell; wherein a radius of curvature of the taper of the tapered portion surrounding the line of contact is greater than the radius of curvature of the spherically shaped region of the socket insert (i.e. sized such that the insert is capable of entering the socket). Additionally, interpretation 2 described in reference to claims 5 and 19-20 supra is applicable to the language of claims 30-31 and 34-35.

22. Regarding claims 26-27 and 32, Serbousek et al. disclose the socket insert is capable of contacting the socket shell solely along the concentric line of contact (paragraph [0029], lines 21-24, and paragraph [0030], lines 1-4).

23. Regarding claims 28-29 and 33, Serbousek et al. disclose the socket insert (14) is monolithic (figure 1).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Serbousek et al. in view of Shelley U.S. patent no. 4,997,447.

26. Regarding claim 13, Serbousek et al. discloses the present invention including at least a portion of an outer surface of the socket shell comprises a mechanism to further facilitate fixation of the shell (paragraph [0042], lines 10-13). However, Serbousek et al. are silent regarding the mechanism to further facilitate fixation of the shell comprises a threaded portion over at least a portion of an outer surface of the socket shell. It is well-known in the art to use a threaded portion over at least a portion of an outer surface of the socket shell to further facilitate fixation of the shell. Shelley teaches a threaded portion over at least a portion of an outer surface of the socket shell (figure 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the outer surface socket shell threaded portion, as taught by Shelley, in the invention disclosed by Serbousek et al. in order to further facilitate fixation of the shell in the acetabulum.

27. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Serbousek et al..

28. Regarding claim 18, Serbousek et al. discloses the present invention, including the line of contact is spaced at varying axial depth from the mouth of the opening of the accommodating space (paragraph [0029], lines 23-24). However, Serbousek et al. is silent regarding the line of

contact is spaced between about 5mm and 15mm from an opening of the accommodating space. It would have been obvious to one of ordinary skill in the art at the time of the invention to space the line of contact between about 5mm and 15mm from an opening of the accommodating space, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is further noted by the Examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to space the line of contact between about 5mm and 15mm from an opening of the accommodating space, since Applicant has not disclosed that spacing the line of contact between 5mm and 15mm solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a line of contact that is spaced at varying axial depths from the mouth of the opening of the accommodating space.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 5-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-28 of copending Application No. 12/296796. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present application and copending application are drawn to a joint socket for a hip joint endoprosthesis, comprising: a socket shell configured for implantation in a bone and comprising a receiving space comprising an inner face; and a socket insert coupleable to the socket shell and configured to accommodate a joint head of a hip prosthesis stem therein, the socket insert comprising a spherical portion comprising a spherical outer face, the spherical portion configured to be received by the receiving space so that the spherical outer face and inner face contact each other concentrically with a rotational axis of the socket shell, the radius of curvature of the inner face being greater than the radius of curvature of the spherical

portion in a region of concentric contact, such that the spherical portion self-lockingly clamps in the receiving space.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA HOFFMAN whose telephone number is (571) 270-1456. The examiner can normally be reached on Monday thru Friday, 10:00 a.m. - 6:30 p.m., Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCIA HOFFMAN/
Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774